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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/521,947 | 02/24/2005 | Kenji Yasuda | TOYA141.001APC 2270 | |
| 20995 7590 08/30/2007 KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614 | | | EXAMINER | |
| | | | HENRY, MICHAEL C | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1623 | |
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| | | NOTIFICATION DATE | DELIVERY MODE | |
| | | | 08/30/2007 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com eOAPilot@kmob.com

| | | Application No. | Applicant(s) | | | |
|--|---|--|--|--|--|--|
| Office Action Summary | | 10/521,947 | YASUDA ET AL. | | | |
| | | Examiner | Art Unit | | | |
| | • | Michael C. Henry | 1623 | | | |
| Period fo | The MAILING DATE of this communication app or Reply | ears on the cover sheet with the c | orrespondence address | | | |
| WHIC - Exter after - If NC - Failu Any | ORTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING DANSIONS of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. period for reply is specified above, the maximum statutory period were to reply within the set or extended period for reply will, by statute, reply received by the Office later than three months after the mailing and patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 66(a). In no event, however, may a reply be tim rill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONEI | N. nely filed the mailing date of this communication. D (35 U.S.C. § 133). | | | |
| Status | | | , | | | |
| 1) | Responsive to communication(s) filed on | • | | | | |
| • | | action is non-final. | | | | |
| 3)□ | Since this application is in condition for allowar | | secution as to the merits is | | | |
| , | closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. | | | | | |
| Dispositi | on of Claims | | | | | |
| 4)🖂 | Claim(s) <u>1-6</u> is/are pending in the application. | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | |
| | Claim(s) is/are allowed. | | | | | |
| 6)⊠ | Claim(s) <u>1-6</u> is/are rejected. | • | • | | | |
| 7) | Claim(s) is/are objected to. | | | | | |
| . 8)□ | Claim(s) are subject to restriction and/or | election requirement. | | | | |
| Application Papers | | | | | | |
| | The specification is objected to by the Examine | • | * | | | |
| 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | |
| Priority u | ınder 35 U.S.C. § 119 | | | | | |
| 12)⊠ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | | |
| a)⊠ All b)□ Some * c)□ None of: | | | | | | |
| 1.⊠ Certified copies of the priority documents have been received. | | | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | | |
| application from the International Bureau (PCT Rule 17.2(a)). | | | | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
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| | 8 | | | | | |
| Attachment(s) | | | | | | |
| 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) | | | | | | |
| 2) 🔲 Notic | 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date | | | | | |
| 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 02/23/05 & 07/24/06. 5) Notice of Informal Patent Application 6) Other: | | | | | | |

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DETAILED ACTION

Claims 1-6 are pending in application

Information Disclosure Statement

The information disclosure statement filed complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file and the information referred to therein has been considered as to the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4 are rejected under 35 U.S.C. 102(b) as being anticipated by De Haen et al. (US 6,007,808).

In claim 1, applicant claims "A composition for promoting bacterial proliferation for selectively proliferating Lactobacillus casei subsp, casei, comprising a dextran. De Haen et al. disclose applicant's composition, comprising a dextran and Lactobacillus casei subsp, casei strain CNCM I-1391 (see col. 4, example 54-63). It should be noted that it is well settled that "intended use" of a composition or product, e.g., promoting bacterial proliferation, does not further limit claims drawn to a composition or product. See, e.g., *Ex parte Marsham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161. Furthermore, it should be noted that De Haen et al.'s composition or product contains the same compound (dextran) and therefore should

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inherently have the same effect of promoting bacterial proliferation for selectively proliferating Lactobacillus casei subsp, casei, as applicant's composition.

In claim 2, applicant claims the composition for promoting bacterial proliferation according to claim 1, further comprising Lactobacillus casei subsp, casei. De Haen et al. disclose applicant's composition, comprising a dextran and Lactobacillus casei subsp, casei strain CNCM I-1391 (see col. 4, example 54-63). It should be noted that it is well settled that "intended use" of a composition or product, e.g., promoting bacterial proliferation, does not further limit claims drawn to a composition or product. See, e.g., *Ex parte Marsham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161. Furthermore, it should be noted that De Haen et al.'s composition or product contains the same compounds or ingredients (dextran and Lactobacillus casei subsp, casei strain CNCM I-1391) and therefore should inherently have the same effect of promoting bacterial proliferation for selectively proliferating Lactobacillus casei subsp, casei, as applicant's composition.

In claim 4, applicant claim a pharmaceutical composition comprising the composition for promoting bacterial proliferation according to claim 2. De Haen et al. disclose applicant's composition, comprising a dextran and Lactobacillus casei subsp, casei strain CNCM I-1391 (see col. 4, example 54-63). It should be noted that it is well settled that "intended use" of a composition or product, e.g., promoting bacterial proliferation, does not further limit claims drawn to a composition or product. See, e.g., *Ex parte Marsham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161. Furthermore, it should be noted that De Haen et al.'s composition or product contains the same compound and therefore should inherently have the same effect of

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promoting bacterial proliferation for selectively proliferating Lactobacillus casei subsp, casei, as applicant's composition.

Claims 1, 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Mitsuhashi et al. (EP 0382355 A2).

In claim 1, applicant claims "A composition for promoting bacterial proliferation for selectively proliferating Lactobacillus casei subsp, casei, comprising a dextran. Mitsuhashi et al. disclose applicant's composition, comprising a dextran (see abstract, see page 3, lines 32-35 and page 8, example 9, lines 4-12, see also claims1, 3, 5). It should be noted that it is well settled that "intended use" of a composition or product, e.g., promoting bacterial proliferation, does not further limit claims drawn to a composition or product. See, e.g., *Ex parte Marsham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161. Furthermore, it should be noted that Mitsuhashi et al.'s composition or product contains the same compound (dextran) and therefore should inherently have the same effect of promoting bacterial proliferation for selectively proliferating Lactobacillus casei subsp, casei, as applicant's composition. In addition, Mitsuhashi et al. disclose that their composition which is orally-ingestible exerts growth-promoting effect for bifid bacteria and can function as a dietary fiber (example 9, lines 4-12).

In claim 3, applicant claims the composition for promoting bacterial proliferation according to claim 1, wherein the dextran has a molecular weight of 2,000 to 40,000,000. Mitsuhashi et al. disclose applicant's composition, comprising a dextran wherein the dextran has a molecular weight of about 90,000 (see page 8, example 9, lines 4-12, page 3, lines 32-35, see abstract and claims 1, 3, 5). It should be noted that it is well settled that "intended use" of a composition or product, e.g., promoting bacterial proliferation, does not further limit claims

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drawn to a composition or product. See, e.g., *Ex parte Marsham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161. Furthermore, it should be noted that Mitsuhashi et al.'s composition or product contains the same compound (dextran) and therefore should inherently have the same effect of promoting bacterial proliferation for selectively proliferating Lactobacillus casei subsp, casei, as applicant's composition. In addition, Mitsuhashi et al. disclose that their composition which is orally-ingestible exerts growth-promoting effect for bifid bacteria and can function as a dietary fiber (example 9, lines 4-12).

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 3 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over De Haen et al. (US 6,007,808).

In claim 3, applicant claims the composition for promoting bacterial proliferation according to claim 1, wherein the dextran has a molecular weight of 2,000 to 40,000,000.

De Haen et al. disclose a composition, comprising a dextran and Lactobacillus casei subsp, casei strain CNCM I-1391 (see col. 4, example 54-63). It should be noted that it is well

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settled that "intended use" of a composition or product, e.g., promoting bacterial proliferation, does not further limit claims drawn to a composition or product. See, e.g., Ex parte Marsham, 2 USPQ2d 1647 (1987) and In re Hack 114, USPQ 161. Furthermore, it should be noted that De Haen et al.'s composition or product contains the same compound (dextran) and therefore should inherently have the same effect of promoting bacterial proliferation for selectively proliferating Lactobacillus casei subsp, casei, as applicant's composition. De Haen et al. does not explicitly disclose the molecular weight of the dextran. But, the silence of De Haen et al. do not mean that their dextran does not have the same molecular weight as applicant's dextran. De Haen et al. anticipates the claims if their dextran has the same molecular weight as applicant's dextran. De Haen et al. renders the claims as being obvious if the molecular weight of their dextran is substantially close the molecular weight of applicant's dextran.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over De Haen et al. (US 6,007,808) in view of Mitsuhashi et al. (EP 382355 A2).

In claim 1, applicant claims "A composition for promoting bacterial proliferation for selectively proliferating Lactobacillus casei subsp, casei, comprising a dextran. In claim 2, applicant claims the composition for promoting bacterial proliferation according to claim 1,

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further comprising Lactobacillus casei subsp, casei. Claims 5 and 6 are drawn to a health food and a feed comprising the composition for promoting bacterial proliferation according to claim 2.

De Haen et al. disclose applicant's composition, comprising a dextran and Lactobacillus casei subsp, casei strain CNCM I-1391 (see col. 4, example 54-63). It should be noted that it is well settled that "intended use" of a composition or product, e.g., promoting bacterial proliferation, does not further limit claims drawn to a composition or product. See, e.g., *Ex parte Marsham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161. Furthermore, it should be noted that De Haen et al.'s composition or product contains the same compound (dextran) and therefore should inherently have the same effect of promoting bacterial proliferation for selectively proliferating Lactobacillus casei subsp, casei, as applicant's composition. Furthermore, De Haen et al. disclose that their composition can be used for the prophylaxis and treatment of gastrointestinal disorders and as a dietetic (see abstract and col. 4, example 54-63).

The difference between applicants' claimed composition and the composition of De Haen et al. is that De Haen et al. do not prepare a health food or feed of said composition.

Mitsuhashi et al. disclose a composition, comprising a dextran (see abstract, see page 3, lines 32-35 and page 8, example 9, lines 4-12, see also claims1, 3, 5). It should be noted that it is well settled that "intended use" of a composition or product, e.g., promoting bacterial proliferation, does not further limit claims drawn to a composition or product. See, e.g., *Ex parte Marsham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161. Furthermore, it should be noted that Mitsuhashi et al.'s composition or product contains the same compound (dextran) and therefore should inherently have the same effect of promoting bacterial proliferation for selectively proliferating Lactobacillus casei subsp. casei, as applicant's composition. In addition,

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Mitsuhashi et al. disclose that their composition which is orally-ingestible exerts growth-promoting effect for bifid bacteria and can function as a dietary fiber (example 9, lines 4-12). Also, Mitsuhashi et al. disclose that pullulan and dextran are advantageously usable for or in health foods, pharmaceuticals, animal feeds and pet foods.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have prepared De Haen et al.'s composition comprising dextran in the form of health foods, pharmaceuticals, animal feeds and pet foods in order to administer it to prevent or treat of gastrointestinal disorders or as a dietetic since Mitsuhashi et al. disclose that dextran are advantageously usable for or in health foods, pharmaceuticals, animal feeds and pet foods.

One having ordinary skill in the art would have been motivated, to prepare De Haen et al.'s composition comprising dextran in the form of health foods, pharmaceuticals, animal feeds and pet foods in order to administer it to prevent or treat of gastrointestinal disorders or as a dietetic since Mitsuhashi et al. disclose that dextran are advantageously usable for or in health foods, pharmaceuticals, animal feeds and pet foods.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry

Shaojia Anna Jiang, Ph.D. Supervisory Patent Examiner Art Unit 1623

August 23, 2007.